

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY
LITIGATION**

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

**DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION
FOR ENTRY OF A LONE PINE CASE MANAGEMENT ORDER**

I. SUMMARY OF REPLY BRIEF

Plaintiffs concede the key facts set forth in Defendants' motion: namely, that many cases have been filed without any medical record review, and when medical records are later collected and analyzed, there is no evidence of digoxin toxicity. Defendants' proposed *Lone Pine* order requiring case-specific evidence of either digoxin toxicity or subtherapeutic digoxin levels is a narrowly tailored request for evidence that should already be in each Plaintiff's attorney's possession per Rule 11 prefilng investigation requirements. Moreover, the limited relief sought is necessary to protect the integrity of the judicial process and the MDL docket, both of which have become severely compromised by the undisputed factual record in this litigation.

Rather than address the facts presented by Defendants, Plaintiffs retreat to a global discussion of *Lone Pine* orders in general. To the extent Plaintiffs tie any of their arguments to this MDL, they are not persuasive. Though Plaintiffs argue that Defendants have not produced all requested documents, Plaintiffs will in fact receive all documents to which they are entitled under this Court's Pretrial Orders and the Federal Rules of Civil Procedure, and those documents are irrelevant to the relief Defendants seek. Defendants' documents will not relate to whether

any individual Plaintiff had digoxin toxicity or a subtherapeutic digoxin level. And, to the extent the Master Complaint encompasses claims of underdosing or overdosing, the necessity of an affidavit from a physician on that issue is required.

II. A LIMITED LONE PINE ORDER AT THIS JUNCTURE OF THE DIGITEK[®] LITIGATION IS NECESSARY.

In their Brief in Support, Defendants presented facts establishing that:

- 1) Responses to Requests for Admission served by various Plaintiffs have revealed that many Plaintiffs' counsel had no medical records in their possession when they filed suit establishing high digoxin levels; nine specific examples were detailed in Defendants' Brief. (Doc. 200, at 2-5.) Plaintiffs did not reply.
- 2) In Exhibit 2 to Defendants' Motion, summaries of 17 cases show no evidence of digoxin toxicity based on medical records collected to date. Plaintiffs did not reply.
- 3) Defendants have incurred substantial costs – well over \$100,000 – in obtaining medical records, only to find in many instances that there is no evidence of digoxin toxicity. (Doc. 200, at 7-8.) Plaintiffs did not reply.
- 4) No Plaintiffs' counsel in any Digitek[®] case in any jurisdiction has yet produced a single double-thick tablet or provided test results from a certified lab that a tablet, within the expiry date, was out of specification (*id.* at 2). Plaintiffs did not reply.
- 5) The FDA determined that there is a small likelihood that any recalled Digitek[®] caused injury to anyone (*id.* at 8). Plaintiffs responded that this was not an “official” finding. (Doc. 214, at 10-11.) But there is no denying that it is the FDA's conclusion regarding potential injury resulting from the recall and that this conclusion generally supports Defendants' motion.

Defendants also argued:

- 1) In likely over a majority of the cases there simply is no evidence of digoxin toxicity reflected by the medical records collected to date by a third-party collection service. (Doc. 200, at 2.) Plaintiffs did not reply.
- 2) The publicity of the recall, and the aggressive advertising and follow-up to the recall, is at the root of this litigation – not actual evidence of ingestion of a defective product (*id.*). Plaintiffs did not reply.

- 3) Absent a *Lone Pine* order, Defendants will continue to expend large amounts of money reviewing medical records, taking depositions, and filing Rule 11 motions in cases that should never have been filed in the first place (*id.* at 8). Again, Plaintiffs did not reply.

These uncontested facts argument cry out for the limited *Lone Pine* relief sought.

III. ARGUMENT

As established in Defendants' motion, *Lone Pine* orders are legitimate and effective case management orders which many courts have used to eliminate spurious claims in pharmaceutical multidistrict litigation. (Doc. 200, at 5-8.) See also *Annotated Manual for Complex Litigation* 4th (2009), §11.34, Author's Comments, at p. 81. Defendants have requested a very narrow *Lone Pine* order in this action: Plaintiffs must provide either an affidavit from a medical expert in each case establishing that there is medical evidence of digoxin toxicity, or produce medical records demonstrating that a treating physician diagnosed digoxin toxicity. (See Docs. 200, 205.)¹ Far from prematurely moving for summary judgment, Defendants simply request information that should already be in Plaintiffs' possession per Rule 11 prefiling investigation requirements.

A. The Requested Lone Pine Order is the Most Efficient and Fair Way to Eliminate the Substantial Number of Infirm Cases in This MDL.

Plaintiffs do not disagree that there are a substantial number of cases filed in this MDL unsupported by any evidence of digoxin overdose or underdose. Plaintiffs claim that they are

¹ Plaintiffs suggest that the Master Complaint is written broadly enough to encompass claims of under-dosing. (Doc. 214, at 13.) To the extent a Plaintiff is really making such a claim, they should likewise be required to provide an affidavit from a physician pointing to evidence in the medical records that doctors were concerned about a subtherapeutic digoxin level. There are medical records produced where digoxin levels are below what are generally assumed to be therapeutic levels, but where no effort was made to increase the level. These low levels can be explained by many things other than a dosage defect, such as a patient not consistently taking the medicine, or being given a lower dose prescription. So Defendants submit that the threshold requirement on this issue should be a demonstrated showing of a medical attempt to raise a level.

“making an effort to self-police cases as shown by the recent increase in case dismissals.” (Doc. 214, at 13.) The recent increase in case dismissals, however, is evidence that a substantial number of these claims were filed without any medical evidence of digoxin toxicity, and the “self-policing” occurs only after Defendants expend considerable time and resources collecting and reviewing medical records, or repeatedly requesting non-existent medical records. Indeed, the 17 case summaries Defendants provided to the Court (Doc. 200, Exh. 2) belie any assertion of “self-policing.”

There are two options to deal with the substantial number of infirmed cases in this MDL: 1) enter a *Lone Pine* order that simply requires Plaintiffs to point to evidence of digoxin overdose or underdose; or 2) require Defendants to continue to expend significant time, money, and personnel resources to collect and analyze medical records in several hundred cases, and then continue the costly Rule 11 procedure under PTO #39 or the costly summary judgment procedure under Rule 56.

The first option is by far the most efficient and fair way to address the issue. First, if a Plaintiff has evidence of digoxin toxicity or underdosage issues, it is not burdensome for Plaintiff to simply point to it. This was more than established by Plaintiff’s counsel, Stanley Jackson, in the *Pinder* case when he did just that – pointed to specific portions of the medical records showing digoxin toxicity. (Doc. No. 203.) In response to Mr. Pinder’s submission, Defendants modified the requested *Lone Pine* relief sought, requesting that Plaintiffs either be required to produce: 1) an affidavit from a medical expert identifying case-specific evidence of digoxin toxicity (referencing specific portions of the medical record); or 2) produce medical records demonstrating that a treating physician diagnosed digoxin toxicity. (Doc. 205.)

In addition, any expense associated with having a medical expert identify the evidence in an affidavit is an expense that a Plaintiff would necessarily have to incur at some point in their case. If Plaintiff has no evidence of digoxin toxicity or underdosing, it is easier, much quicker, and cheaper for Plaintiff to determine this now, and dismiss the suit, rather than continue to force Defendants to collect and analyze medical records in several hundred cases, and initiate the Rule 11 or Rule 56 mechanisms. And a simple review of an individual Plaintiff's medical records, as Mr. Jackson did, is every Plaintiff's lawyer's threshold obligation. Indeed, this approach is consistent with the Plaintiffs' burdens under the Federal Rules of Civil Procedure. It is Plaintiffs' burden to bear the cost of screening and evaluating their cases under Rule 11 *before* filing suit. It is not Defendants' burden to bear those costs *after* such cases are inappropriately filed. But that is exactly what has been happening here.

Aside from efficiency and cost, a limited *Lone Pine* order is also the fairest option. Defendants are not requiring Plaintiffs to marshal all of their proof on every essential element of every claim.² The *Lone Pine* order that Defendants request is obviously not a premature summary judgment motion. Plaintiffs concede that they should have had some evidence of digoxin toxicity before filing suit; it is undisputed that a recall letter alone is not a good-faith inquiry under Rule 11.

² Many courts have issued much more extensive *Lone Pine* orders than that requested here. See, e.g., *Grant v. E.I. DuPont De Nemours & Co.*, 1993 WL 146634, at *4 (E.D. N.C. Feb. 17, 1993) (issuing *Lone Pine* order requiring plaintiffs to provide expert medical opinions ruling out other causes); *Cottle v. Superior Court of Ventura County*, 3 Cal. App. 4th 1367, 1372 (Cal. Ct. App. 1992) (issuing *Lone Pine* order requiring plaintiffs to identify (1) the toxic substance; (2) date or dates of exposure; (3) method of exposure; (4) nature of plaintiff's injury; and (5) each medical expert who would support the plaintiff's personal injury claims).

Instead, Plaintiffs claim that because the Actavis Defendants have not yet produced every document requested, this is good reason not to enter a *Lone Pine* Order. But this argument fails because the documents which Defendants will be producing do not relate to whether a Plaintiff has digoxin toxicity. Such information will not be found in company records regarding the manufacture of Digitek®; it is within medical records which Plaintiffs should have evaluated before they filed suit.

In short, there is no question that the narrow *Lone Pine* Order requested is the most efficient and fair mechanism “to identify and cull potentially meritless claims and streamline litigation in complex cases involving numerous claimants.” *See Baker v. Chevron USA, Inc.*, 2007 WL 315346, at *1 (S.D. Ohio Jan. 30, 2007). Culling meritless claims early in the litigation is one of the basic purposes of a *Lone Pine* order. *Id.* A *Lone Pine* order becomes incrementally more efficient and necessary with every additional spurious claim, and the discovery that has taken place so far shows that a *Lone Pine* order is necessary in this MDL at this time.

B. The Court Should Enter the Limited Lone Pine Order To Protect the Integrity of the Judicial Process And its Own Docket.

Aside from the undisputed history of this MDL and the factual record Defendants presented to the Court, it is also in the Court’s interest to protect the integrity of the judicial process and its own docket. Given the facts discovered thus far, it is likely – at this juncture alone – that a majority of the cases on this Court’s docket are meritless. The entry of the limited *Lone Pine* Order requested will send a message to all lawyers in this litigation, and those contemplating the filing of new cases, that this Court expects cases to be adequately screened under Rule 11 before they are filed. And this imposes no additional burden or obligation on any

individual attorney beyond what is already required under Rule 11, as that rule has been interpreted in this Circuit.

The requests for admission permitted by PTO 39 and 41 have resulted in numerous dismissals since many plaintiffs have dismissed their cases rather than admit that they had not reviewed medical records before filing suit. So these orders have been effective in eliminating some obviously infirmed cases from the docket. Unfortunately, they are quickly replaced by new filings that likewise did not go through the requisite Rule 11 screening process. And there are many more cases where the medical records conclusively show that there is no Digoxin toxicity. So the Court should address that issue by granting the limited relief requested.

C. Plaintiffs' Attempt To Distinguish the Case Law Defendants Cite Is Misleading.

Without question, some courts that have entered *Lone Pine* Orders have done so in cases involving numerous defendants and products, and at various stages of the litigation. *See, e.g., Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986). And in some cases, *Lone Pine* orders are uncontested. *See, e.g., Baker v. Chevron USA, Inc.*, 2007 WL 315346 (S.D. Ohio Jan. 30, 2007); *Grant*, 1993 WL 146634, at *1. But the case law cannot be cabined into only those categories in which the facts of those cases present.

Rather than address the actual *Lone Pine* at issue, Plaintiffs superficially parse the decisions of several courts that have entered unrelated *Lone Pine* orders into three distinct categories. (Doc. 214, at 5-9.) First, Plaintiffs argue that *Lone Pine* orders are only appropriate after extensive discovery has occurred. But as Defendants have already established, many courts enter *Lone Pine* orders early in litigation to weed out meritless claims, and where the facts specific to the case deem it appropriate at that time. *See, e.g., Lone Pine*, 1986 WL 637507, at *3-4 (*Lone Pine* case management order was issued “at the outset of the suit”); *see also Acuna v.*

Brown & Root, Inc., 200 F.3d 335, 338, 340 (5th Cir. 2000) (*Lone Pine* case management orders were issued “pre-discovery”); *Abbatiello v. Monsanto Co.*, 569 F. Supp. 2d 351, 354 (S.D.N.Y. 2008) (“The purpose of Lone Pine style CMOs, requiring *early* individual causation expert evidence, is to protect defendants and the Court from the burdens associated with potentially non-meritorious mass tort claims.”) (emphasis added); *Baker*, 2007 WL 315346, at *1 (suit was filed in April 2005 and *Lone Pine* case management order was entered in August 2005 requiring plaintiffs to disclose evidence of causation “prior to formal discovery”).

Second, Plaintiffs argue that *Lone Pine* orders are only used when there are multiple defendants, but this is not true either. *See, e.g., Baker*, 2007 WL 315346, at *1 (*Lone Pine* order entered in an action where 360 residents sued Chevron USA, Inc. and its subsidiaries). In *Cottle*, the court entered a *Lone Pine* order noting that there were 175 claimants, but the court did not find any significance in the number or identity of the defendants. 3 Cal. App. 4th at 1371 n.1 (“For the purpose of this petition, we can discern no reason to identify the various defendants other than to refer to them at times.”) Even though *Lone Pine* orders may be useful where there are multiple Defendants and product identification is in issue, *see, e.g., Acuna v. Brown & Root, Inc.*, 200 F.3d 335, *Lone Pine* orders are also useful in complex cases involving numerous claimants who may have filed baseless suits. *Baker*, 2007 WL 315346, at *1 (“The basic purpose of a Lone Pine order is to identify and cull potentially meritless claims and streamline litigation in complex cases involving numerous claimants, such as this one.”).

Third, Plaintiffs point out that *Lone Pine* orders are uncontested in some cases. If these cases demonstrate anything, they show that *Lone Pine* orders may be so necessary and appropriate that plaintiffs do not or cannot contest them. Plaintiffs in this case should have similarly recognized the fairness and efficiency of Defendants’ limited request.

In short, whether the entry of a broad or limited *Lone Pine* order is appropriate in a particular case or MDL is an individualized inquiry into the facts of the litigation at issue, and an individualized determination as to whether the facts justify the entry of a *Lone Pine* order at a particular point in time. Given the history of this litigation, Defendants submit that now is that time, particularly where Plaintiffs have not contested the factual record on which Defendants' motion is based.

D. Plaintiffs' Assertion That The "Vast Majority" of Courts Have Not Issued Lone Pine Orders Is Inaccurate.

As noted above, instead of addressing whether a *Lone Pine* order is appropriate in this case, Plaintiffs attack the viability of *Lone Pine* orders in general by suggesting that the "vast majority" of courts have rejected the case management tool. (Doc. 214, at 11.) Plaintiffs assert that the "four orders cited by Defendants are dwarfed by the volume of MDL proceedings in which a *Lone Pine* or functionally equivalent case management order did not issue." (*Id.*, at 5.) In support, Plaintiffs name (without citation) fifteen medical device and pharmaceutical MDLs. (*Id.*, at 5 n.1.) Presumably, this list is meant to demonstrate to the Court that the "vast majority" of MDL courts have decided against using *Lone Pine* orders. Not so.

After reviewing the string of MDL dockets cited by Plaintiffs, the "vast majority" of them never even involved a *request* for a *Lone Pine* order. In fact, Defendants were only able to find one case where the court actually considered a *Lone Pine* request. And in that MDL, the court merely denied the motion "as premature." *See In re: Seroquel Products Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB (M.D. Fla. filed Nov. 16, 2007).

As for Plaintiffs' cited cases in which the court actually considered a *Lone Pine* motion, each decided not to enter a *Lone Pine* order based upon the specific circumstances of that case. *See Kirsch v. Delta Dental of New Jersey, Inc.*, Case No. CIVA 07-186 SRC MAS, 2008

WL 441860, at *3 (D.N.J. Feb. 14, 2008) (holding that “[t]he case currently before the Court is markedly different” from cases before other courts in which *Lone Pine* orders had been adopted); *Morgan v. Ford Motor Co.*, No. 06-1080(JAP), 2007 WL 1456154, at *10 (D.N.J. May 17, 2007) (declining to enter a *Lone Pine* order “based on the positions of the parties and the circumstances of this particular case”); *Simeone v. Girard City Bd. of Educ.*, 872 N.E.2d 344, ¶ 46 (Ohio Ct. App. 2007) (holding that the *Lone Pine* “circumstances are not present in this case”); *Estate of Mancini v. Lexington Ins. Co.*, No. L-2228-03, 2006 WL 3359429 (N.J. Super. A.D. Nov. 21, 2006) (reversing a *Lone Pine* order where appellant challenged its appropriateness “in a case such as this”). And in one case, the court simply concluded that a motion to adopt a *Lone Pine* order was “premature.” See *In re 2004 DuPont Litig.*, No. 04-229-DLB, 2006 WL 5097316 (E.D. Ky. Mar. 8, 2006).

For example, in *Simeone v. Girard City Board of Education*, 13 students, their parents, and four teachers brought a lawsuit against the defendants involved in the building of the Girard Intermediate School after the school was closed due to health problems. See *Simeone*, 872 N.E.2d at ¶¶ 2-3. Unlike the *Lone Pine* Order requested in our Motion, the *Lone Pine* order in *Simeone* required, *inter alia*, sworn expert testimony as to general and specific causation. See *Id.* at ¶¶ 36-37. Plaintiffs in *Simeone* responded with affidavits from their experts indicating that they could not meet the *Lone Pine* requirements without receiving some discovery. *Id.* at ¶ 7. The *Simeone* court concluded that “[t]he timing of the issuance of the *Lone Pine* order in this case effectively and inappropriately supplanted the summary judgment procedure in Civ.R. 56.” *Id.* at ¶ 53 (emphasis added). As explained in detail above, the same cannot be said for the facts in this MDL, or the limited relief requested.

Similarly, in *Morgan v. Ford Motor Company*, another case prominently cited by Plaintiffs, the court concluded that a *Lone Pine* order was not appropriate given the circumstances of that case. *See Morgan*, 2007 WL 1456154, at *7 (noting that *Lone Pine* orders “are not appropriate in all circumstances”). A contamination case, the court in *Morgan* decided against a *Lone Pine* order after considering the circumstances of its case compared to *Lone Pine*. *Id.* at *8-9. The *Morgan* court found two important distinctions that led the court not to enter a *Lone Pine* order. *Id.* at *8. First, unlike *Lone Pine*, where the EPA found no contamination, the contamination in *Morgan* was significant enough that the site was added to the National Priorities List, known as the Superfund Site list. *Id.* Also, unlike *Lone Pine* where some of the plaintiffs lived 20 miles from the site, in *Morgan* literally hundreds of people lived within a mile of the contamination. *Id.* The *Morgan* court decided against a *Lone Pine* order “based on the positions of the parties and the circumstances of this particular case” *Id.* at *10.

In each of the cases cited by Plaintiffs, the individual courts concluded that a *Lone Pine* order was either not appropriate given the circumstances of that particular case, or at that particular time. Plaintiffs’ choice to effectively ignore Defendants’ detailed explanation for why a *Lone Pine* order is appropriate now, given the history and circumstances of this case, cannot operate to preclude what is plainly warranted and necessary now.

IV. CONCLUSION

Defendants’ limited *Lone Pine* order is fair and efficient. Plaintiffs should have some medical evidence of digoxin toxicity or under-dosage; a substantial number of the cases filed in the MDL are not supported by any medical evidence of digoxin toxicity or under-dosage; and in the absence of a *Lone Pine* order, Defendants will continue to expend a staggering amount of money, time, and resources taking on Plaintiffs’ threshold burden by reviewing medical records,

taking depositions, and filing Rule 11 or 56 motions in cases that should never have been filed in the first place.

ALLEN GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com

Attorney for Defendants

SHOOK, HARDY & BACON LLP

Harvey L. Kaplan, CO-LEAD COUNSEL
Madeleine M. McDonough, CO-LEAD COUNSEL
2555 Grand Blvd.
Kansas City, Missouri 64108-2613
Tel: (816) 559-2214
Fax: (816) 421-5547
E-mail: hkaplan@shb.com
E-mail: mmcdonough@shb.com

*Attorneys for Mylan Pharmaceuticals Inc.,
Mylan Bertek Pharmaceuticals Inc., and UDL
Laboratories, Inc.*

Respectfully submitted,

TUCKER ELLIS & WEST LLP

By: s/Richard A. Dean

Richard A. Dean, CO-LEAD COUNSEL
Matthew P. Moriarty, CO-LEAD COUNSEL
Kristen L. Mayer
925 Euclid Avenue, Suite 1150
Cleveland, Oh 44115-1414
Tel: (216) 592-5000
Fax: (216) 592-5009
E-mail: richard.dean@tuckerellis.com
matthew.moriarty@tuckerellis.com
kristen.mayer@tuckerellis.com

*Attorneys for Defendants Actavis Totowa LLC,
Actavis Inc., and Actavis Elizabeth LLC*

CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2009, a copy of the foregoing **Defendants' Reply Brief in Support of Motion for Entry of a Lone Pine Case Management Order** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

ALLEN GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com

Attorney for Defendants

SHOOK, HARDY & BACON LLP

Harvey L. Kaplan, CO-LEAD COUNSEL
Madeleine M. McDonough, CO-LEAD
COUNSEL
2555 Grand Blvd.
Kansas City, Missouri 64108-2613
Tel: (816) 559-2214
Fax: (816) 421-5547
E-mail: hkaplan@shb.com
E-mail: mmcdonough@shb.com

*Attorneys for Mylan Pharmaceuticals Inc.,
Mylan Bertek Pharmaceuticals Inc., and UDL
Laboratories, Inc.*

TUCKER ELLIS & WEST LLP

By: s/Richard A. Dean

Richard A. Dean, CO-LEAD COUNSEL
Matthew P. Moriarty, CO-LEAD
COUNSEL
Kristen L. Mayer
925 Euclid Avenue, Suite 1150
Cleveland, Oh 44115-1414
Tel: (216) 592-5000
Fax: (216) 592-5009

E-mail: richard.dean@tuckerellis.com
matthew.moriarty@tuckerellis.com
kristen.mayer@tuckerellis.com

*Attorneys for Defendants Actavis Totowa LLC,
Actavis Inc., and Actavis Elizabeth LLC*

073021.000031.1067499.1